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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,169	03/31/2004	Pamela J. Ferreira	ALD 046.10	7505
74866	7590	04/27/2010		
Intarcia Therapeutics, Inc. ATTN: Barbara G. McClung 24650 Industrial Blvd Hayward, CA 94545			EXAMINER AL-AWADI, DANAH J	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 04/27/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,169	<b>Applicant(s)</b> FEREIRA ET AL.	
	<b>Examiner</b> DANAH AL-AWADI	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 page/03/31/2004; 2 pages/05/13/2005; 2 pages</u>            | 6) <input type="checkbox"/> Other: _____                          |
| <u>05/15/2006; 1 page/06/29/2006; 2 pages/08/21/2006; 2 pages 07/11/2008; 1</u>        |   |
| <u>pages 07/11/2008; 3 pages/07/11/2208.</u>   |   |



## **DETAILED ACTION**

### ***Information Disclosure Statement***

Information Disclosure statements filed on 31 March 2004, 13 May 2005, 15 May 2006, 29 June 2006, 21 August 2006, and 11 July 2008, are acknowledged and have been reviewed.

### ***Claim Rejections- 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8-10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dionne et al. US Patent 6, 132, 420.

Dionne et al. US Patent 6, 132, 420 (hereafter the '420 patent) teaches an osmotic delivery device with a reservoir having at least one drug delivery orifice; an osmotic composition contained within the reservoir; and a movable piston disposed within the reservoir between the osmotic composition and the drug formulation; and a semipermeable membrane ( abstract, the paragraph of line 54 column 2). With regards to the organic liquid, the '420 patent teaches

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osmotic agents which are organic liquids (PEG 400 and peanut oil) (the paragraph of line 42 column 5).

The '420 patent teaches that osmotic delivery systems include a capsule having walls which selectively pass water into an interior of the capsule which contains a water attracting osmotic agent ( i.e. a preloaded membrane comprising a semipermeable material and an organic liquid filler material contained within the semipermeable material).

With regards to claims 8-10, these limitations are would be inherent to a device containing a preloaded membrane.

### ***Claim Rejections- 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-7, and 11, 13, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dionne et al. US Patent 6, 132, 420.

The '420 patent has been discussed supra.

Regarding a second filler material the '420 patent teaches discloses multiple osmotic agents which would be in and therefore around the osmotic composition. With regards to multiple osmotic agents 2144.06 of the MPEP teaches "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven.

All the osmotic agents would substantially be the same because they all share the quality of being osmotic agents. Furthermore, the '420 patent discloses PEG molecules of different lengths which would be substantially the same.

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With regards to claims 5-7, these limitations are would be inherent to a device containing a preloaded membrane. Until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the device containing a preloaded membrane which is instantly claimed.

With regards to the saturation of the preloaded membrane, the '420 patent discloses that capsule may contain only an osmotic agent in which case the osmotic agent would be present at a saturated level.

With regards to having a plug that is positioned within an opening in the reservoir, the '420 patent teaches inclusion of a membrane plug that is placed in an opening in the capsule. The water enters the capsule through the membrane plug.

With regards to claim 15, these limitations have been addressed. In addition regarding the plug position, the '420 patent teaches "the osmotic ally active agent and the compartment in which it resides may be referred to as an "osmotic engine." A membrane plug is then placed in an opening in the capsule through which the tablet was inserted. The water enters the capsule through the membrane plug. Alternatively, water may enter directly through the capsule walls if they are permeable to water". Therefore, the plug is positioned such that it adjacent to the osmotic composition. Additionally, according to the instant specification the terms "preload" and "preloaded" indicate that a desired amount of liquid filler is absorbed into a semipermeable material included in the preloaded membrane before the osmotic pump with which the preloaded membrane is associated is delivered to an environment of operation. Even though it is absorbed into, this a product by process definition that has no bearing on the finished product.

*CORRESPONDENCE*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615